DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems, Nederland B.V.
% Ms. Susan Quick
Regulatory Affairs Specialist
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
CLEVELAND OH 44143

May 8, 2015

Re: K143606
Trade/Device Name: Multiband Sense
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: April 17, 2015
Received: April 20, 2015

Dear Ms. Quick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143606

Device Name
MultiBand SENSE

Indications for Use *(Describe)*

MultiBand SENSE is a software option intended for use on Achieva and Ingenia 1.5T & 3.0T MR Systems. It's indicated for use in magnetic resonance imaging of the brain for BOLD fMRI. MultiBand SENSE consists of an acquisition and reconstruction technique allowing simultaneous excitation of multiple volumes to accelerate imaging acquisition times or increasing coverage or resolution without increasing scan time.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PHILIPS

Philips Medical Systems Nederland B.V.

510(k) Summary

MultiBand SENSE

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. General Information
21 CFR 807.92 (a)(1), (2)

Company Name:	Philips Medical Systems Nederland B.V.
Address:	Veenpluis 4-6 5684 PC Best The Netherlands
Registration No.:	3003768277
Contact Person:	Susan Quick 595 Miner Rd Cleveland, Oh 44143 Tel: (440)-483-2291 Fax: (440)-483-4799 E-mail: susan.quick@philips.com
Prepared (date):	2014 December 12
Trade Name of Device:	MultiBand SENSE
Classification:	Class II
Regulatory Section:	Magnetic Resonance Diagnostic Device. 892.1000
Product Code:	90LNH

21 CFR 807.92(a)(3):Legally marketed predicate device to which substantial equivalence is claimed:

1. Primary Predicate Device: SENSE
   Manufacturer: Philips Medical Systems Nederland BV
   Predicate Device k#: K110151

21 CFR 807.92(a)(4): Description of the device that is the subject of this premarket notification:

Summary of functions of the device and its major components

The MultiBand SENSE technique enables simultaneous excitation and acquisition of multiple volumes or slices for the purpose of speeding up acquisition times or increasing coverage or resolution at constant scan time. The simultaneous excitation is done using a multi-band radio-frequency pulse. The unfolding of the simultaneously acquired volumes is done using the SENSE algorithm. The unfolding process (solving the linear equation of the SENSE algorithm) is improved by introducing a linear phase over k-space in the volume direction resulting in a spatial shift of the aliased pixels. The phase shift is applied by additional blip-gradients in the slice direction or switching between different RF pulses, and compensated for in reconstruction by a translation of the coil sensitivity data before the SENSE unfolding.
The feature consists of:

- Modulated RF pulses exciting 2 or more slices
- Blip-gradients to introduce a phase shift for improved unfolding
- New parameterization of the SENSE calculations
- Shifting coil sensitivities in reconstruction to correct for linear phase shift.

MultiBand SENSE is supported on the following systems:

- 3.0T Ingenia
- 3.0T Achieva
- 1.5T Ingenia
- 1.5T Achieva

The functionality is supported on all available gradient performance levels. Optimized protocols will be provided for the different performance points. MultiBand SENSE is supported on the centralized data acquisition systems of the Achieva systems as well as the digitally networked data acquisition system of the Ingenia systems. The data acquisition system is fully transparent to the MultiBand SENSE pulse sequences and reconstructions.

21 CFR 807.92(a)(5): Intended Use

MultiBand SENSE is a software option intended for use on Achieva and Ingenia l.5T & 3.OT MR Systems. It's indicated for use in magnetic resonance imaging of the brain for BOLD fMRI. MultiBand SENSE consists of an acquisition and reconstruction technique allowing simultaneous excitation of multiple volumes to accelerate imaging acquisition times or increasing coverage or resolution without increasing scan time.

21 CFR 807.92(a)(6): Technological Characteristics:

The main functional units in the software are:

- Methods (acquisition of MR signals by means of MR pulse sequences)
- Reconstruction (transforming the MR signals to images)
- Patient Administration (storing of the images in the database and providing access)
- Viewing (display of images)

The technical impact of the feature MultiBand SENSE comprises:

- Methods: Introduction of a modulated RF pulse. Apply blipped gradients. Provide new parameterization for SENSE reconstruction.

- Reconstruction: Read new parameterization of SENSE calculations. Shift coil sensitivities before SENSE calculations.

No off-the-shelf software is used for the feature MultiBand SENSE. The off-the-shelf software used in the basic MR system is cleared. MultiBand SENSE is not designed to be connected to an external network.

MultiBand SENSE does not require any change of the hardware platform. The extension introduced by Multiband SENSE, are in methods pulse sequence code, and in reconstruction only for a new parameterization of a cleared SENSE unfolding calculation. Those run on the host computer characteristics :

- Manufacturer: HP; Model: Z420; Processor clock: 3.5 GHz; RAM: 64 GB RAM; Processors: six core with hyper threading

- Operating system: Windows 7, 64 bits

The only new element for the operator of the Multiband SENSE feature in this clinical routine workflow is:
- Protocol selection: The operator selects an ExamCard with Multiband SENSE protocols
- Planscan phase: Optionally the operator may want to change the predefined Multiband acceleration factor.

All other steps are not changed. The generated image types can be viewed, post-processed, printed and archived as any other image type.

21 CFR 807.92(b)(1): Brief discussion of nonclinical tests submitted, referenced or relied on in this premarket notification:

MultiBand SENSE has been verified to function with the Achieva and Ingenia 1.5T and 3.0T MR systems.

The verification testing showed the MultiBand SENSE examcards could be loaded, the correct parameters were listed for each scan, MultiBand SENSE and SENSE functioned properly together, the average SNR deviation was <10% for every slice, all scans ran properly and images were provided.

The conclusion from this report is:
All the tests performed for MultiBand SENSE were successful. Workflow was smooth and no problems occurred.
No defects were reported.

21 CFR 807.92(b)(2): Brief discussion of clinical tests submitted, referenced or relied on in this premarket notification:

Clinical user needs are tested as part of validation. The validation testing showed that for fMRI scans with MultiBand SENSE enabled the scan time was shorter when compared to fMRI with MultiBand disabled for the same number of slices. Also the user could increase the number of slices when using MultiBand SENSE under the scan time recorded without MultiBand SENSE.

The conclusion from testing the device is:
The clinical validation of MultiBand SENSE has completed successfully. All clinical user needs have passed for MultiBand SENSE on the Achieva and Ingenia 1.5T and 3T systems. No new hazards were identified.

21 CFR 807.92(b)(3): The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section:

The nonclinical and clinical tests have demonstrated that the device is safe and works according to its intended use**.**

MultiBand SENSE software does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers MultiBand SENSE Software to be substantially equivalent to the above mentioned predicate device.